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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,674	10/17/2005	Kaw Yan Chua	15700.0002	1823
27890	7590	08/20/2008		
STEP TOE & JOHNSON LLP 1330 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036				
EXAMINER				
ROONEY, NORA MAUREEN				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
08/20/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,674

**Applicant(s)**

CHUA ET AL.

**Examiner**

NORA M. ROONEY

**Art Unit**

1644

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 138-169 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 138-169 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s) Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s) Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Species Election*

1. Applicant's election of Invention 7 (Cancelled claim 100) drawn to a method of preparing polypeptide capable of modulating an immune response against a molecule, the polypeptide comprising: (a) a first portion being an Fvc polypeptide (SEQ ID NO: 6), a fragment thereof comprising at least 20 amino acids or a polypeptide having at least 70% sequence identity thereto, which polypeptide or fragment comprises immunomodulatory activity; and (b) a second portion being a molecule against which the modulation of the immune response is desired, wherein the second portion comprises a specific allergen in the reply filed on 05/20/2008 with traverse is acknowledged.

The traversal is on the grounds that "applicants respectfully request that Inventions 7, 9 and 11 be combined into a single group because in each, the molecule is an allergen, a viral antigen, or a tumor antigen. No justification was provided to restrict the molecule into three separate groups. Thus, Applicants propose that Invention 7, 9 and 11 be combined into a single Group for restriction purposes, and that if an election of species is necessary, Applicants elect the invention in which the molecule is an allergen." This is not found persuasive because polypeptides comprising allergens, viral antigens and tumor antigens have different structures, physiochemical properties and modes of operation. Therefore, each group of polypeptides is patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 138-142 and 147-157 read on the elected invention drawn to a method of preparing polypeptide capable of modulating an immune response against a molecule, the polypeptide comprising: (a) a first portion being an Fve polypeptide (SEQ ID NO: 6), a fragment thereof comprising at least 20 amino acids or a polypeptide having at least 70% sequence identity thereto, which polypeptide or fragment comprises immunomodulatory activity; and (b) a second portion being a molecule against which the modulation of the immune response is desired, wherein the second portion comprises a specific allergen.
3. Claims 143-146 and 158-169 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/20/2008.
4. In view of the newly added claims filed on 05/20/2008, the following species election is set forth below.
5. This application contains claims directed to the following patentably distinct species:

Applicant is further required to elect a single specific polypeptide comprising:

a single specific first portion comprising an allergen or allergen fragment as set forth in claims 140 or 142 (Der p 1, Der f 1, Blot 1, Eur m1, Lep d 1, Der p 2, Der f2, Blo t 2, Eur m 2, Lep d 2, Blot 5, Der p 5, Der f 5, Eur m 5, Lep d 5, Der p 15, Der f 15, Blot 15, Eur

m 15, Lep d 15, Bet v 1, Bet v 2, Phl p 1, Phl p 2, antigen E from ragweed Fel d 1, Asp fl Asp f2 or Asp f3); **and**

a single specific second portion comprising a single specific Fve polypeptide having a specific sequence with specified mutations as recited in claims 138, 141 and 147-151 and 153-155

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 18, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

/Maher M. Haddad/  
Maher M. Haddad, Ph.D.  
Primary Examiner,  
Art Unit 1644